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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/225,478	04/08/1994	DONALD B. KOHN		9305
27162	7590	09/01/2004	EXAMINER	
CARELLA, BYRNE, BAIN, GILFILLAN, CECCHI, STEWART & OLSTEIN 5 BECKER FARM ROAD ROSELAND, NJ 07068			WEHBE, ANNE MARIE SABRINA	
		ART UNIT		PAPER NUMBER
		1632		50

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	08/225,478	KOHN ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Marie S. Wehbe	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 6-15, and 23-26 is/are allowed.
- 6) Claim(s) 1-3,5,21 and 22 is/are rejected.
- 7) Claim(s) 4 is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | Paper No(s)/Mail Date. ____ .   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: ____ .                                   |

## **DETAILED ACTION**

A Decision on Appeal by the Board of Patent Appeals and Interferences was mailed to the applicants on 3/31/04. In the Decision, the Board reversed the rejection of appealed claims 1-5 and 21-22 under 35 U.S.C. 112, first paragraph, made by the previous examiner of record. This examiner of record in this case has changed, see page 4. In reviewing the application for allowance, the new examiner of record identified prior art not previously made of record which applies to instant claims 1-3, 5, and 21-22. As a result, prosecution in this case has been reopened and the finality of the office action mailed to applicants on 8/20/98 has been withdrawn. Claims 1-15 and 21-26 are pending in the instant application.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the

reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-3, 5, and 21-22 are newly rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 5,911,983 (6/15/99), hereafter referred to as Barranger et al.. The applicant claims a method of expressing a therapeutic agent in a human comprising administering autologous CD34+ cells obtained from cord blood to said human, said autologous CD34+ cells having been genetically engineered to include at least once nucleic acid encoding a therapeutic agent. The applicant further claims said methods wherein the nucleic acid is contained in a retroviral vector, or wherein the CD34+ cells are administered in an amount from about  $5 \times 10^5$  /kg-  $5 \times 10^6$  /kg.

Barranger et al. teaches methods for providing biologically active glucocerebrosidase to an individual with Gaucher disease comprising isolating autologous human CD34+ hematopoietic progenitor cells, transducing the cells with a retroviral vector encoding glucocerebrosidase, and transplanting the transduced cells back into the individual with Gaucher disease (Barranger et al., column 28, claims 13-16). While the claims in the Barranger patent recite that the human CD34+ cells are derived from bone marrow, the specification clearly teaches that other sources of human CD34+ cells can be used in the methods of treating Gaucher disease, including CD34+ cells derived from cord blood as exemplified in Figure 28 (see also Barranger et al., column 6). In addition, Barranger et al. teaches that the reintroduction of  $2 \times 10^6$  /kg CD34+ cells into patients (Barranger et al., column 26, lines 55-64). Thus, by teaching all the limitations of the claims as written, Barranger et al. anticipates the instant invention as claimed.

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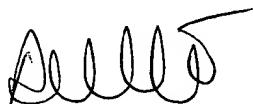
Claim 4 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 6-15 and 23-26 are considered free of the prior art of record and allowable at this time.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER



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